

UNITED STATES DEPARTMENT OF JUSTICE DRUG ENFORCEMENT ADMINISTRATION

Docket No. 13-40 HOUSE OF MEDICINE DECISION AND ORDER

On October 2, 2013, Administrative Law Judge (ALJ) Christopher B. McNeil issued the attached Recommended Decision (R.D.). Therein, the ALJ found that there was no dispute over the material fact that Respondent does not possess authority under the laws of California, the State in which it has applied for a DEA Certificate of Registration as a Retail Pharmacy, to dispense controlled substances. R.D. at 5-6. Accordingly, the ALJ held that Applicant does not meet the statutory definition of a practitioner, see 21 U.S.C. § 802(21), and therefore is not entitled to be registered under 21 U.S.C. § 823(f). Id. at 6. The ALJ thus granted the Government's Motion for Summary Disposition and recommended that the Administrator deny Respondent's application. Id. at 7. Neither party filed exceptions to the Recommended Decision.

Having reviewed the record, I have decided to adopt the ALJ's Recommended Decision in its entirety except as discussed below. Accordingly, I deny Respondent's application.

ORDER

Pursuant to the authority vested in me by 21 U.S.C. § 823(f), as well as 28 CFR 0.100(b) and 0.104, I order that the application of House of Medicine for a DEA Certificate of Registration as a Retail Pharmacy be, and it hereby is, denied. This Order is effective

received by DEA two days later. See id. at n.5. Having reviewed the record, I find that the actual date on which Respondent filed its hearing request was September 5, 2013. See Letter of Jahangir S. Janfaza to Hearing Clerk, Office of Administrative Law Judges (Sept. 3, 2013).

¹ In the R.D., the ALJ found that the Order to Show Cause was issued on August 6, 2013. R.D. at 2. The ALJ then found that "[o]n December 26, 2012, Respondent . . . filed a timely request for hearing." Id. However, in a footnote, the ALJ cited Respondent's request for a hearing and noted that it was dated September 3, 2013 and

immediately.

Dated: January 17, 2014.

Thomas M. Harrigan, Deputy Administrator.

ORDER GRANTING THE GOVERNMENT'S MOTION FOR SUMMARY DISPOSITION

AND

RECOMMENDED RULING, FINDINGS OF FACT, CONCLUSIONS OF LAW, AND DECISION OF THE ADMINISTRATIVE LAW JUDGE

Nature of the Case and Procedural History

Christopher B. McNeil, Administrative Law Judge. On June 16, 2009, House of Medicine, the respondent in this case, submitted an application to the Drug Enforcement Administration seeking a new DEA retail pharmacy registration.¹ Respondent, acting through its owner and apparent sole proprietor, Jahangir S. Janfaza, sought this registration for use at 9025 Wilshire Boulevard, Suite 200, Beverly Hills, California.² The pending DEA application number for this application is W09156272A.³

On August 6, 2013, the Deputy Administrator of the Drug Enforcement Administration,
Office of Diversion Control, filed an Order to Show Cause proposing to deny the application
pursuant to 21 U.S.C. § 823(f). As grounds for revocation, the Government alleges that
Respondent does not have the authority to handle controlled substances in the State of California
and it alleges that Respondent's registration would be inconsistent with the public interest.⁴

On December 26, 2012, Respondent, through its sole owner, Jahangir S. Janfaza, filed a timely request for hearing.⁵ Respondent does not dispute that the required professional license that had permitted House of Medicine to provide retail pharmacy services in California expired effective March 13, 2013, and does not dispute that it has not submitted a renewal or new

¹ Order to Show Cause dated August 6, 2013 at 3.

² <u>Id</u>.

 $^{^{3}\}overline{\text{Id}}$. at 1.

¹ Id.

⁵ Respondent's Request for Hearing dated September 3, 2013, received by DEA September 5, 2013, at 1-2.

application for such license. He argues, however, he has provided pharmacy services to the community for 50 years, that he is attempting to resolve a pending dispute with the California pharmacy licensing authority, that such a resolution requires that he pay \$57,900 in fines and other costs to that licensing authority, and that due to financial hardship due to medical conditions he has not been able to reach a resolution with that licensing authority.⁷

In my order of September 6, 2013, I directed the Government to provide evidence to support the allegation that Respondent lacks state authority to handle controlled substances. I received the Government's Motion for Summary Disposition on September 19, 2013, with proof of service upon Respondent, accompanied by supporting documentation. The factual premise relied upon by the Government in support of its motion is that Respondent does not have a pharmacy license issued by the California State Board of Pharmacy, the state in which Respondent seeks to be registered.⁸

In my Order of September 6, 2013, I provided to Respondent the opportunity to respond to the Government's Motion for Summary Disposition. That response was due by September 25, 2013.9 I have not received Respondent's response, nor have I received any request to enlarge the time for filing such a response.

Although Respondent has not directly responded to the factual and legal premises raised by the Government, its initial pleading does set forth facts and arguments in support of its application for a Certificate of Registration. Drawing what I can from the premises appearing in Respondent's request for a hearing, I find as follows.

⁶ <u>Id</u>. ⁷ <u>Id</u>. at 2.

⁸ Government's Motion for Summary Disposition at 1.

⁹ Order for Briefing on Allegations Concerning Respondent's Lack of State Authority at 2.

<u>Issue</u>

The substantial issue raised by the Government rests on an undisputed fact. The Government asserts that Respondent's application must be summarily denied because Respondent does not have a pharmacy license issued by the state in which it intends to operate. Under DEA precedent, an application for a retail-pharmacy DEA Certificate of Registration must be summarily denied if the applicant is not authorized to handle controlled substances in the state in which it seeks DEA registration. Unless from the pleadings now before me there is a material issue regarding Respondent's authority to handle controlled substances in California, the application must be denied summarily, without a hearing.

Respondent's Contentions

Respondent sought a hearing on its application to explain why it currently does not have a pharmacy license in California. This explanation is clear and cogent, and was succinctly presented by Mr. Janfaza in Respondent's request for Hearing dated September 3, 2013. In this letter, Mr. Janfaza asked for a hearing, and asked that it be held close to his home, due to his age and medical condition. He explained that he is 76 years old, and currently is receiving disability benefits after undergoing emergency heart surgery in August 2012. His medical condition has left him unable to work, and his condition is described in detail through supporting documentation accompanying Respondent's request for a Hearing. Mr. Janfaza noted as well

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¹⁰ See 21 U.S.C. §§ 801(21), 823(f), 824(a)(3); see also Deanwood Pharmacy, 68 Fed. Reg. 41662-01 (DEA July 14, 2003); Wayne D. Longmore, M.D., 77 Fed. Reg. 67669-02 (DEA November 13, 2012); Alan H. Olefsky, M.D., 72 Fed. Reg. 42127-01 (DEA August 1, 2007); Layfe Robert Anthony, M.D., 67 Fed. Reg. 15811 (DEA May 20, 2002); George Thomas, PA-C, 64 Fed. Reg. 15811-02 (DEA April 1, 1999); Shahid Musud Siddiqui, M.D., 61 Fed. Reg. 14818-02 (DEA April 4, 1996); Michael D. Lawton, M.D., 59 Fed. Reg. 17792-01 (DEA April 14, 1994); Abraham A. Chaplan, M.D., 57 Fed. Reg. 55280-03 (DEA November 24, 1992). See also Bio Diagnosis Int'l, 78 Fed. Reg. 39327-03, 39331 (DEA July 1, 2013) (distinguishing distributor applicants from other "practitioners" in the context of summary disposition analysis).

¹¹ Respondent's Request for hearing at 1-2.

¹² <u>Id</u>.

 $^{^{13}}$ $\overline{\text{Id}}$. at 2.

 $^{^{13}}$ $\overline{\underline{Id}}$.

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the medical condition of his wife, whose diagnosis of breast cancer and related surgery in 2012 contributed to the poor financial condition of his family.¹⁵

Mr. Janfaza also explained the connection between his family's financial condition and the circumstances that currently prevent him from obtaining a license to operate a pharmacy in California. 16 He stated that he currently owes the California State Board of Pharmacy \$28,950 personally, and that House of Medicine owes \$28,950 as well, resulting in a debt of \$57,900. He explained that he offered to make payments of \$500 per month (or \$6,000 per year) toward retiring this obligation, but that "it appears that they are not willing to accept my hardship as noted herein." 17 Mr. Janfaza concluded by observing that "I have suffered greatly and lost most if not all of my business over the last few years. Any assistance from your office will be greatly appreciated."18

Scope of Authority

The case before me is presented under a grant of authority to recommend that the Administrator either grant or deny Respondent's application for a DEA retail-pharmacy license. Pursuant to 21 U.S.C. § 823(f), the DEA may grant such an application only to a pharmacy "practitioner." Under 21 U.S.C. § 802(21), a "practitioner" must be "licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he practices or does research, to distribute [or] dispense . . . controlled substance[s.]" Given this statutory language, the DEA Administrator does not have the authority under the Controlled Substances Act to grant a registration to a practitioner if that practitioner is not authorized by to dispense controlled substances. 19

^{15 &}lt;u>Id</u>. 16 <u>Id</u>. 17 <u>Id</u>.

¹⁹ See Abraham A. Chaplan, M.D., 57 Fed. Reg. 55280-03, 55280 (DEA 1992), and cases cited therein.

Facts

Given this body of law, the material fact here, indeed the sole fact of consequence, is whether Respondent is authorized by the State of California to dispense controlled substances. Where, as here, no material fact is in dispute, there is no need for an evidentiary hearing and summary disposition is appropriate.²⁰ The sole question of fact before me can be addressed, and has been addressed, by the pleadings submitted to me by the parties. Our record includes a declaration by Mr. Janfaza that his authority and that of Respondent to dispense controlled substances in California expired in 2012 and has not been renewed.²¹ The reasons for nonrenewal are not material, given the statutory language set forth above.

Analysis, Findings of Fact and Conclusions of Law

In determining whether to grant the Government's motion for summary disposition, I am required to apply the principle of law that holds such a motion may be granted in an administrative proceeding if no material question of fact exists:

It is settled law that when no fact question is involved or the facts are agreed, a plenary, adversary administrative proceeding involving evidence, cross-examination of witnesses, etc., is not obligatory - even though a pertinent statute prescribes a hearing. In such situations, the rationale is that Congress does not intend administrative agencies to perform meaningless tasks (citations omitted). ²²

In this context, I am further guided by prior decisions before the DEA involving certificate holders who lacked licenses to distribute or dispense controlled substances. On the issue of whether an evidentiary hearing is required, "it is well settled that when there is no question of material fact involved, there is no need for a plenary, administrative hearing."²³

²⁰ See Michael G. Dolin, M.D., 65 Fed. Reg. 5661 (DEA February 4, 2000); see also Philip E. Kirk, M.D., 48 Fed. Reg. 32887 (DEA July 19, 1983), aff'd sub nom. Kirk v. Mullen, 749 F.2d 297 (6th Cir. 1984).

²¹ Respondent's Request for Hearing at 1.

²² NLRB v. International Assoc. of Bridge, 549 F.2d 634, 638 (9th Cir. 1977) (quoting <u>United States v. Consolidated Mines & Smelting Co., Ltd.</u>, 455 F.2d 432, 453 (9th Cir. 1971)).

²³ See Michael G. Dolin, M.D., 65 Fed. Reg. 5661 (DEA February 4, 2000); <u>Jesus R. Juarez, M.D.</u>, 62 Fed. Reg.

²³ See Michael G. Dolin, M.D., 65 Fed. Reg. 5661 (DEA February 4, 2000); Jesus R. Juarez, M.D., 62 Fed. Reg. 14945 (DEA March 28, 1997); see also Philip E. Kirk, M.D., 48 Fed. Reg. 32887 (DEA July 19, 1983), aff'd sub

Under this guidance, the Government's motion must be sustained unless a material fact question has been presented.

The Government argues that the sole determinative fact now before me is that Respondent lacks a California pharmacy license. I agree. In order for a pharmacy to receive a DEA registration authorizing it to dispense controlled substances under 21 U.S.C. § 823(f), it must meet the definition of "practitioner" as found in the Controlled Substances Act.²⁴ Such an entity must be "licensed, registered, or otherwise permitted by . . . the jurisdiction in which he practices . . . to distribute, dispense, [or] administer . . . a controlled substance in the course of professional practice." Delegating to the Attorney General the authority to determine who may or may not be registered to perform these duties, Congress permitted such registration only to "practitioners" as defined by the Controlled Substances Act.²⁶

As cited by the Government in its Motion for Summary Disposition, there is substantial authority both through agency precedent and through decisions of courts in review of that precedent, holding that an application for a retail pharmacy DEA registration is dependent upon the applicant having a state license to dispense controlled substances.²⁷ Under the doctrine before me, the Government meets its burden of establishing grounds to deny an application for registration upon sufficient proof establishing the applicant's state pharmacy license has expired and has not been renewed. That proof is in the record before me, and it warrants the summary denial of Respondent's application for a DEA Certificate of Registration.

I am mindful of the arguments raised by Respondent in its Request for a Hearing, including the fact that Respondent's lack of a pharmacy license is based on financial obligations

nom. Kirk v. Mullen, 749 F.2d 297 (6th Cir. 1984).

²⁴ 21 U.S.C. § 802(21).

²⁵ Id

²⁶ 21 U.S.C. § 823(f).

²⁷ Government's Motion for Summary Disposition at 4 and cases cited therein.

Respondent and Mr. Janfaza have incurred with the California Board of Pharmacy, and with the difficulties Mr. Janfaza faces in meeting those obligations. These difficulties do not, however, change the fact that without a state pharmacy license, Respondent is not a "practitioner" and cannot be granted a Certificate of Registration.

Some care should be taken to assure the parties that the actions taken in this administrative proceeding conform to constitutional requirements. I have examined the parties' contentions with an eye towards ensuring all tenets of due process have been adhered to. There is, however, no authority for me to evaluate the facts that underlie Respondent's contentions. While the details of these circumstances may explain why Mr. Janfaza has been unable to renew his pharmacy's California license, the facts or allegations in his request for a hearing are not material in the administrative proceedings now before the DEA. In the proceedings now before me, the only material question was answered by Respondent in its Request for Hearing. Further, while the Order to Show Cause sets forth a non-exhaustive summary of facts and law relevant to a determination that granting this application would be inconsistent with the public interest under 21 U.S.C. § 823(f), the conclusion, order and recommendation that follow are based solely on a finding that Respondent is not a "practitioner" as that term is defined by 21 U.S.C. § 802(21), and I make no finding regarding whether granting this application would or would not be inconsistent with the public interest.

Order Granting the Government's Motion for Summary Disposition and Recommendation

I find there is no genuine dispute regarding whether Respondent is a "practitioner" as that term is defined by 21 U.S.C. 802(21), and that based on the record the Government has established that Respondent is not a practitioner and is not authorized to dispense controlled substances in the state in which it seeks to operate under a DEA Certificate of Registration. I find

no other material facts at issue, for the reasons set forth in the Government's Motion for

Summary Disposition. Accordingly, I GRANT the Government's Motion for Summary

Disposition.

Upon this finding, I ORDER that this case be forwarded to the Administrator for final

disposition and I RECOMMEND the Administrator DENY Respondent's application for a

DEA Certificate of Registration.

Date: October 2, 2013

s/CHRISTOPHER B. MCNEIL Administrative Law Judge

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